Remarks

Paragraph 1 of the detailed listing objects to the computer readable form previously filed. The attached error report says the computer readable form is defective for not being saved in ASCII text and indicates statements under 37 C.F.R. 1.821(f) and 1.821(g) have not been supplied.

Reconsideration is requested. Enclosed in a CD holder is a substitute computer readable form as required by 37 C.F.R. 1.821(e) saved in ASCII text and a paper sequence listing under 37 C.F.R. 1.821(e) corresponding thereto. Enclosed is a Verification Summary Report.

Enclosed are statements Under 37 C.F.R. 1.821(f) and 37 C.F.R. 1.821(g).

It is submitted that the requirements under 37 C.F.R. 1.821 – 1.825 are complied with. Reconsideration is requested.

Claims 1-12 are in the case. Claims 1 and 2 are being prosecuted. Claims 3-12 are withdrawn from consideration.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as not being enabled on the basis that there is no evidence that triple-stranded (triplex) structures will form between RNA and double stranded DNA in chromatin where connectron symmetries are identified. The rejection takes the position that the specification needs to show and does not show that connectrons form within cells and have an effect on gene expression.

Reconsideration is requested.

A connectron is a four sequence relationship between two adjacent sequences that are produced as RNA when a gene or a non-coding element transcribes and two non-adjacent sequences which are double-stranded DNA. Related Application No. 09/866,925 is directed to identifying connectrons. Decision by the Board of Appeals in that application seems to indicate that computer mediated identification of connectrons is set forth so as to meet the description and enablement requirements of 37 U.S.C. 112, first paragraph. The Office Action at page 4 of the detailed action states that the "specification provides guidance to identify connectron symmetries in genome sequences." The claims are directed to computer mediated selective deletion and/or addition of connectrons of a genome. The contention in the Office Action is that such computer mediated selective deletion and/or addition is not described and enabled in accordance with 35 C.F.R. 112, first paragraph. What this position ignores is that such deletion/addition per se is part of the discovery/identification process and that no further use need be evidenced. The invention is directed to discovering what is in genomes and of the ability to computer mediate changes in genomes. It is submitted that this constitutes utility and such use as may be required by 35 U.S.C. 112. The undersigned refers to this act of discovering as computational/computer-mediated "microscopy." No one would contend that the act of using a microscope for discovery purposes doesn't constitute an enabled use or that modification of what is discovered does not constitute further discovery. It is submitted that in the same way the discovery of claims 1 and 2 is an enabled use per se.

The PTO is contending that something further is required, namely proof that triplex structures will form and have an effect on gene expression. The undersigned disagrees as indicated above.

But even if relying on identification/discovery alone is not sufficient, the PTO position is defective because the law is that applicant does not have to prove that triplex formation occurs within cells and has an effect on gene expression. Rather the burden of proof is on the PTO to prove that discovered four-sequence relationships will not result in triplex formation and effect on genome behavior. Casting doubt is not even enough. See Ex parte Reese, 40 U.S.P.Q.2d 1221 (Pat. Off. Bd. App. Int. 1996); In re Dinh-Hguyen, 181 U.S.P.Q. 46,47 (C.C.P.A. 1974) and In re Gardiner, 177 U.S.P.Q. 396, 397 (C.C.P.A.). The PTO has not met this burden.

Moreover pro forma application of the Wands factors as carried out here does not cause the burden of the PTO to change to Applicant. No case says that such does.

The Wands factors are directed to showing lack of enablement in the facts of Wands as described in In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Consider also Ex Parte Forman, 230 U.S.P.Q. 546,547 (Bd. App. and int. 1986) relied on by Wands for the Wands factor.

The specific issue in Wands involved whether monoclonal antibodies necessary to practice the immunoassay method claimed were enabled without undue experimentation when practice involved screening negative hybridomas to find those that produced the desired antibodies.

In Foreman a question was whether mutant strains of S. typhis necessary for an

oral vaccine were enabled when there was a lack of guidance leading to predictable results for obtaining mutant S. typhis.

The instant case differs from Wands and Foreman because no issue has been raised about treating agents or treating regimen. Thus the specific issues present in Wands and Foreman are not present here.

The issue according to Wand and Foreman is whether the application here describes how to computer mediate identification of connectrons and modification thereof. There is no contention that it does not.

The issue presented by the Office Action although not stated as such is whether the claims have utility, i.e. is whether connectrons and modified connectrons have utility.

It is noted that the applicant has applied the algorithm of 09/366,925 to more than three hundred prokaryotic and Archae genomes and at least a dozen eukaryotic genomes. In every genome that has been examined, connectrons have been found. It is submitted that logic indicates that these have useful purpose. It is submitted that this is basis for a presumption that the connections are useful. The PTO has not overcome this presumption. It is submitted that this is independent basis for allowance.

Allowance is requested.

While the undersigned believes strongly that computer mediated detection provides enablement and that no physical evidence is necessary to show triplex structures form and have an effect on genome behavior the inventor is designing an experiment to show use of connectrons to control gene expression. This is set forth in

the Appendix hereto. The undersigned asks herewith if the examiner will consider whether success in said experiment will overcome the rejection.

A Request for Continued Examination is being filed concurrently herewith.

Respectfully submitted,
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PROPOSED EXPERIMENT

The idea for a critical experiment proving the existence and utility of connectrons was first proposed by Dr. Malathi Ragunathan - professor in the School of Medicine at the University of Madras in Chennai, Tamil Nadu, India.

The experiment is being implemented by Dr. Kevin Fitzgerald S.J. - professor in the School of Medicine at Georgetown University in Washington D.C.

A commercial source of the standard E. coli has been purchased with a plasmid that contains the Kanamycin resistance gene. Any E. coli without this plasmid and Kanamycin resistance gene will die in the presence of the drug Kanamycin in the culture medium. If the E. coli have the plasmid with this gene and the gene is able to transcribe the DNA into RNA for subsequent translation into protein, then the cells of the culture will survive. If the Kanamycin gene is prevented from either being promoted for transcription or the transcription is blocked before the complete transcript for the protein is formed, then the E. coli cells in the culture will die.

The same plasmid has a promoter which initiates transcription when galactose is present in the culture medium.

We have developed a computer algorithm that takes the Kanamycin resistance gene DNA sequence and finds two 40-base non-adjacent sequences that do not occur any other place in the E. coli genome. The two 40-base sequences are then synthesized as a single 80-base double-stranded piece of DNA and then inserted after the galactose promoter. When galactose is present in the culture medium, the galactose promoter will cause the synthesis of an 80-base piece of RNA.

We assert that this specific piece of RNA will bind to only two places in the plasmid DNA and nowhere else in the E. coli genome. This specific piece of RNA will bind to two places in the Kanamycin resistance gene to form two triple-stranded Hoogsteen helices. The transcription of the Kanamycin resistance gene will be interrupted before the complete RNA transcript for the protein is formed. Because this Kanamycin resistance protein is not being translated the E. coli will not have the resistance to this drug and the cells will die.